UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,305	06/06/2002	Gene H MacDonald	5470.276	1963

20792 7590 12/28/2004

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,305	MACDONALD ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-45 are currently pending in the application and are addressed herein.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, 21-26, drawn to a method of introducing and expressing a nucleotide sequence in a cell comprising contacting a cell with and alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector, wherein the heterologous nucleotide sequence encodes an immunogen from an infectious agent .

Group II, claim(s) 1-15, 17, 21-26, drawn to a method of introducing and expressing a nucleotide sequence in a cell comprising contacting a cell with and alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector, wherein the heterologous nucleotide sequence encodes a cancer/tumor antigen.

Group III, claim(s) 1-14, 18, 19, 21-26, drawn to a method of introducing and expressing a nucleotide sequence in a cell comprising contacting a cell with and alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector, wherein the heterologous nucleotide sequence encodes a therapeutic protein, such as a cytokine.

Group IV, claim(s) 1-13, 21-26, drawn to a method of introducing and expressing a nucleotide sequence in a cell comprising contacting a cell with and alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector, wherein the heterologous nucleotide sequence encodes an RNA.

Group V, claim(s) 27-32, drawn to a method of administering a nucleotide sequence to a subject comprising administering an alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector to the subject.

Group VI, claim(s) 33-34, drawn to a method of administering a nucleotide sequence to a subject comprising administering an alphavirus vector comprising a heterologous nucleotide sequence to a subject that has antibodies that specifically bind to the alphavirus vector.

Group VII, claim(s) 35, drawn to a method of administering a nucleotide sequence to a subject comprising contacting a cell with an alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector and administering the cell to a subject.

Group VIII, claim(s) 36, drawn to a method of enhancing the introduction and expression of a nucleotide sequence in a cell comprising contacting a cell with an alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector whereby introduction and expression of the heterologous nucleotide sequence in the cell is enhanced in the presence of the antibody as compared with the absence of the antibody.

Group IX, claim(s) 37-39, 42, drawn to a method of producing an immune response in a subject comprising an alphavirus vector comprising a heterologous nucleotide sequence encoding an immunogen and an antibody that specifically binds to the alphavirus vector and further administering a cytokine to the subject whereby an immune response is produced against the immunogen in the subject.

Group X, claim(s) 37-38, 40-42, drawn to a method of producing an immune response in a subject comprising an alphavirus vector comprising a heterologous nucleotide sequence encoding an immunogen and an antibody that specifically binds to the alphavirus vector and further administering a second heterologous nucleotide sequence encoding a cytokine.

Group XI, claim(s) 43, drawn to a method of producing an immune response in a subject comprising an alphavirus vector comprising a heterologous nucleotide sequence encoding an immunogen to a subject that has antibodies that specifically bind to the alphavirus vector.

Group XII, claim(s) 44, drawn to a method of producing an immune response in a subject comprising contacting a cell with an alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector and administering the cell to a subject whereby an immune response is produced against the immunogen in the subject.

Group XIII, claim(s) 45, drawn to a pharmaceutical formulation comprising an alphavirus vector comprising a heterologous nucleotide sequence and an antibody that specifically binds to the alphavirus vector in a pharmaceutically acceptable carrier.

It is noted that claims 40 and 41 are drawn to a method comprising administering a nucleotide sequence encoding a cytokine to a subject, but are dependent on claim 39, which is drawn to a method comprising administering a cytokine to a subject. Administering a cytokine is interpreted as administering a polypeptide that is a cytokine to the subject. Therefore, claims 40

and 41 improperly depend on claim 39 because claims 40 and 41 do not encompass administering a cytokine polypeptide to a subject. Since the claims 39 is a different method from claims 40-41, the claims have been separated into different groups. However, claims 40-41 are currently improperly dependent on claim 39. Claims 40-41 should be amended such that they are not improper dependent claims.

It is noted that 37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I, is considered the main invention.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

In order for a technical feature to be considered special, it must be novel. In the instant case, it was determined that the technical feature linking the claims is the method of introducing and expressing a nucleotide sequence in a cell by administering an alphavirus vector comprising a heterologous nucleotide sequence to a subject that has antibodies that specifically bind to the vector (e.g., see claim 36) because it is the broadest method and it is encompassed by all the other methods. However, the technical feature linking all of the claims is not novel because it was taught in the prior art. Specifically, WO 99/25858 (Parrington, et al., published May, 1999) teaches a method wherein an alphaviral vector comprising a heterologous nucleotide sequence encoding a paramyxovirus polypeptide was introduced into a subject, and then administered to the subject again at a later time point (e.g., as a boosting administration). (e.g., see decription of figure 4, the Examoles and the claims). The second administration to the subject constitutes administering the alphaviral vector to a subject that has antibodies to the vector. As such, the technical feature is not novel, and thus it is not a special technical feature and no special technical feature links the claims.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cells are as follows (see claim 3):

Macrophages, monocytes, dendritic cells, phagocytic leukocytes, B lymphocytes and endothelial cells.

The species of RNAs are as follows (see claim 20):

Antisense nucleic acid, RNA that effects spliceosome mediated trans-splicing, and a guide RNA.

The species of subjects are as follows (see claim 29):

Primate, bovine, ovine, caprine, porcine, equine, feline, canine, lagomorph, and rodent.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 3 correspond to the species of cells. Claims 1, 20 correspond to the species of RNAs. Claims 27, 29 correspond to the species of subjects.

The following claim(s) are generic: 1 and 3 are generic for the species of cells, claims 1 and 20 are generic for the species of RNAs and claims 27 and 29 are generic for the species of subjects.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: in order for a technical feature to be special, it must be novel. In the instant case, all of the claimed species were well known in the art. Therefore, the technical feature is not special and, as such, no special technical feature links the claimed species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635

DAVE TRONG NGUYEN
PRIMARY EXAMINER